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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,739	08/01/2003	Yung-Ming Chen	50623.325	3887

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EXAMINER

CHANG, ROSIE YUH LOO

ART UNIT	PAPER NUMBER
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1762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/632,739	Applicant(s) CHEN ET AL.	
	Examiner ROSIE YL CHANG	Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 15, 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-20 and 28-33 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/24/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant states in the second preliminary amendment filed on June 04, 2004 that this application, No. 10/623,739, is a CIP of application of the prior-filed application, No. 09/470,559 and No. 09/621,123 and a division of Application No. 09/750,655. The new subject matter of "a composition comprising ethylene vinyl alcohol copolymer, isopropyl alcohol and water to coat a prosthesis" was not described in either prior-filed CIP applications.

Accordingly, claims 14, 16-20, 28-33 do not entitle the benefit of the prior applications. The prior date for the instant application is 12/28/2000.

Oath/Declaration

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention.

It is unclear to the Examiner; the instant application No. 10/632,739 is declared as a CIP of No. 09/470,559 (12/23/1999) and No. 09/621,123 (7/21/2000) and also as a divisional application of No. 09/750,655 (12/28/2000), while Application No. 09/750,655 is also declared as a CIP of Application No. 09/470,559 and Application No. 09/621,123.

A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Claim Objections

Claim 17 is objected to because of the following informalities:

The phrase "less than the melting temperature" on line 3 of claim 17 is unclear. For the purpose of examination, "less than the melting temperature" is assumed.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(1)

Claims 14, 17, 20, 31-33 are rejected under 35 U.S.C. 103 (a) as being anticipated by Misoo et al. (US 5,863,645).

Misoo et al. ('645) teach a method of coating (col. 6, line 1-3) a medical article having blood compatibility (col. 4, line 66-67 and col. 5, line 1-2) in the shape of hollow fiber membrane (col. 6, line 7-8), by applying a composition comprising (col. 7, line 24-26) a hydrophilic copolymer, i.e. ethylene-vinyl alcohol copolymer (col. 11, line 27-32) and a solvent to the prosthesis to form a coating, the solvent comprising (col. 7, line 34-49) isopropyl alcohol and water, wherein the coating is formed when the solvent is removed from the composition (col. 11, line 44-47). Misoo et al. ('645) do not specifically teach the medical article having blood compatibility is an implantable medical device such as prosthesis.

Examiner notes that medical article such as prosthesis would obviously require compatibility with blood in order to be implanted in the blood vessel. Therefore, it would have been obvious to one of ordinary skill in the art to coat prosthesis in the coating method of Misoo et al. ('645), because Misoo et al. teach the coating material is safe for coating an implantable medical article contact blood.

As for claim 17:

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Misoo et al. ('645) teach (col. 11, line 44-47) drying the composition of ethylene-vinyl alcohol copolymer (col. 11, line 27-28) on prosthesis by applying hot air of 60C. Additionally, Misoo et al. ('645) teach (col. 9, line 35-38) the copolymer composition may be dried at a temperature not higher than 120.degree. C., and it may be most preferably dried at a temperature from 40 degree to 70 degree C. Examiner notes that Applicants specification teaches drying the same copolymer, EVOH coated prosthesis (Instant Application, Example 5) to about 50C, thus the drying temperature in the teaching of Misoo et al. ('645) would be the same range as required by Applicant, i.e. drying the coating to a temperature greater than the glass transition temperature of the copolymer and less than the melting temperature of the copolymer, absent a showing or argument to the contrary.

As for claim 20:

Misoo et al. ('645) teach (col. 7, line 3-4) the copolymer having not less than 20% by mole of ethylene. Misoo et al. ('645) fail to specifically teach the copolymer having 27% to 29% by mole of ethylene. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a copolymer having 27% to 29% by mole of ethylene, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See M.P.E.P. 2144.05 IIA. This would not be expected to provide a patentable feature, and would have been obvious for one ordinary skill in the art to perform.

As for claim 31-33:

Misoo et al. ('645) teach (col. 7, line 51-56) the mixing ratio of the water-soluble solvent, i.e. IPA, to water may be selected at any ratio as long as the solubility of the copolymer is not decreased, and it may also depend on the type of copolymer used; Misoo et al. ('645) fail to teach the ratio of IPA to water is in the range between about 1 to 1 or 40/60 or 45/55. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a solvent system that having IPA to water ratio of about 1 to 1 or 40/60 or 45/55 (for example , a 50-50 ratio), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See M.P.E.P. 2144.05 IIA. This would not be expected to provide a patentable feature, and would have been obvious for one ordinary skill in the art to perform.

(2)

Claims 16, 18-19, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misoo et al. ('645) in view of Hossainy et al. (US 6,451,373).

Misoo et al. ('645) teach that which is disclosed above.

Misoo et al. ('645) coating a prosthesis with a composition of ethylene vinyl alcohol copolymer and aqueous solvents to render the blood compatibility of the medical article. Misoo et al. ('645) do not specifically teach the hollow prosthesis is a balloon-expandable stent or a graft. Hossainy et al. ('373) teach to coat (col. 7, line 24) prosthesis with a composition of ethylene vinyl alcohol copolymer (col. 10, line 50-53) and a polar organic solvent to form (col. 5, line 54-58) a

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biocompatible and bioabsorbable film on the prosthesis surface. Additionally, Hossainy et al. ('373) teach the examples of prosthesis (col.3, line 36-38) include self-expandable stents, which are (col. 1, line 38) cylindrical or tubular in shape and grafts. Since both Misoo et al. and Hossainy coat a prosthesis with ethylene vinyl alcohol copolymer, it would have been obvious to one having ordinary skill in the art at the time the invention was made to coat Hossainy's cylindrical stent with the composition of ethylene vinyl alcohol copolymer taught by Misoo et al. ('645) with expectation of successful result. Because Hossainy et al. ('373) teach that hydrophilic ethylene vinyl alcohol copolymer is suitable and safe for coating a stent, it would have been expected that hydrophilic copolymer composition of Misoo et al. ('645) would be effective, safe and suitable for Hossainy's coating a stent.

As for claims 18-19:

Hossainy et al. ('373) teach the composition additionally comprises an active agent, i.e paclitaxel or actinomycin D (col. 4, line 34-60), for inhibiting restenosis of a blood vessel, wherein the active agent is contained (col. 3, line 64-66) in the coating formed on the prosthesis.

As for claim 28:

Hossainy et al. ('373) teach (col. 8, line 15-18) the composition is applied to (col. 3, line 43) metallic surface of the prosthesis.

As for claims 29-30:

Hossainy et al. ('373) teach (col. 9, line 53-63) the composition is applied to a drug reservoir layer deposited of the prosthesis.

Allowable Subject Matter


There is no allowable subject matter at this time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROSIE YL CHANG whose telephone number is 571-272-6466. The examiner can normally be reached on MONDAY TO FRIDAY 7: 00AM TO 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIMOTHY MEEKS can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


**KEITH HENDRICKS
PRIMARY EXAMINER**